

PART III
PLAINTIFFS'
EXHIBITS

EXHIBIT 13



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genetics institute

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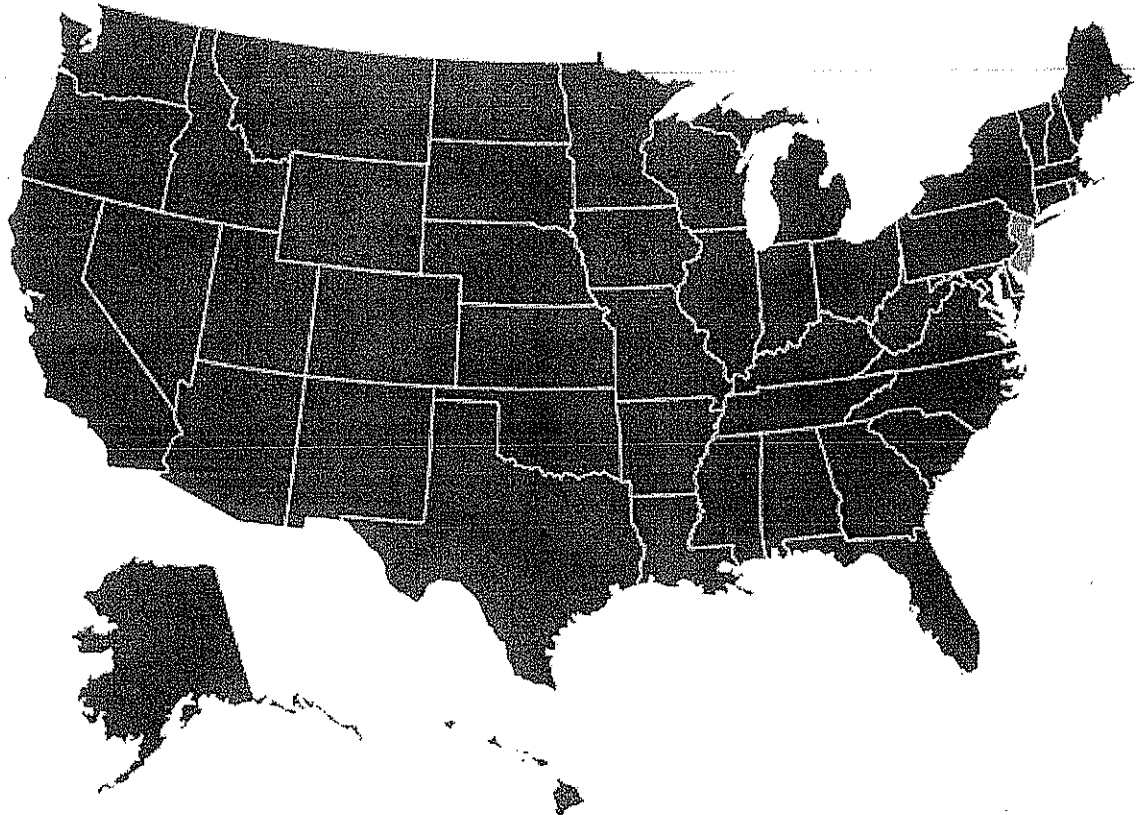


EXHIBIT 14

STEPHEN N. LEUCHTMAN, P.C.

Stephen N. Leuchtman

23855 Northwestern Highway

Southfield, MI 48075

(248) 948-9696, Ext. 143

Attorneys for Defendants—Genesis Genetics Institute, LLC and Mark R. Hughes, M.D.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

CHAYA GROSSBAUM and
MENACHEM GROSSBAUM, her
spouse, individually and as guardians
ad litem of the infant ROSIE
GROSSBAUM,

Plaintiffs,

vs.

GENESIS GENETICS INSTITUTE,
LLC, of the State of Michigan,
MARK R. HUGHES, NEW YORK
UNIVERSITY SCHOOL OF MEDICINE
and NEW YORK UNIVERSITY
HOSPITALS CENTER, both
corporations in the State of New York,
ABC CORPS. 1-10, and JOHN DOES
1-10,

Defendants.

DOCKET NO. 07-CV-1359 (HAA)

CIVIL ACTION

**ANSWERS TO INTERROGATORIES
ON BEHALF OF DEFENDANTS
GENESIS GENETICS, LLC and
MARK R. HUGHES, M.D.**

1. (a) Shannon Wiltse
 - (a) November 1, 2003 to January 1, 2005,; then May 1, 2006 to present.
 - (b) See above.
 - © Masters in Genetics Counseling, Certified Genetics Counselor
- (b) Matt Studt
 - (a) July 23, 2003 to present
 - (b) No answer required.
 - © Lab Scientist with degree in Biosciences.

- © Susan Brown
 - (a) November 3, 2003 to present.
 - (b) No answer required.
- © PhD in Molecular Biology.

2. Defendants Hughes and Genesis Genetics, LLC object to this interrogatory as oppressive and burdensome, as needlessly interfering with existing advantageous business relationships, as calling for violations of privilege and confidentiality, and as not calculated to lead to the discovery of relevant evidence. There are hundreds of such entities with which Genesis Genetics has worked over the years.
3. This has been provided.
4. No.
5. None known, other than those referenced in the chart which has been provided.
6. See attached.
7. Eve Rubell, Jose Bergero, et al. v. University of Southern California School of Medicine, et al.
Superior Court of the State of California, County of Los Angeles
Case no. BC 325496
Settled as to R. Paulson, M.D. and USC Reproductive Endocrinology and Infertility—amount confidential
Defendants Genesis Genetics and Hughes were voluntarily dismissed without payment before trial
The case was tried as to M. Francis, M.D. and USC Keck School of Medicine, resulting in a defense verdict circa April, 2007.
Plaintiffs' attorney: Arlan A Cohen, M.D., J.D. —
Attorney for Paulson and USC Reproductive Endocrinology and Infertility: Richard D. Carroll
Attorney for Francis and USC Keck School of Medicine: Patrick E. Stockalper
Attorney for Genesis Genetics and Hughes: Stephen N. Leuchtman

Ardemis Assadourian, Romeo Piro v. Pacific Fertility Center et al.
Superior Court of the State of California, County of San Francisco
Case no. CGCo7-464474
Pending
Attorney for Plaintiffs: Khaldoun Baghdadi
Attorney for Genesis Genetics: Stephen N. Leuchtman
Attorney for non-Genesis defendants: Robert M. Slattery

Amy Paule et al. v. Mark Hughes, M.D. et al.

Circuit Court of Tennessee, Thirtieth Judicial District at Memphis

Case No. CT-001773-08

Pending

Plaintiffs' attorney: Gary K. Smith

Attorney for Hughes and Genesis Genetics: James T. McColgan

Attorneys for other parties not readily available but can be obtained from Smith

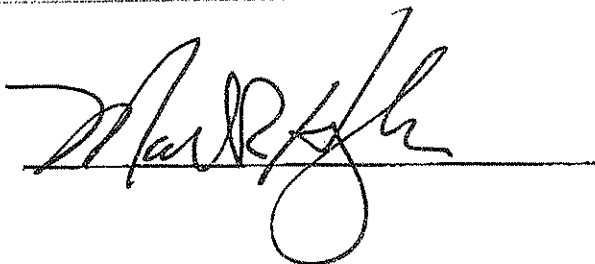
8. None.
9. None as to this case. As to the other cases, this information is equally available to the plaintiffs. Further, this Interrogatory is objected to as interfering with professional and fiduciary relationships, as being in violation of the work product doctrine, and as not calculated to lead to the discovery of relevant evidence.
10.
 - (a) See attached.
 - (b) See attached.
 - © I have never had staff privileges with any hospital other than those connected with my medical training.
 - (d) Other than in my medical training, I have never practiced medicine.
 - (e) None.
 - (f) No.
11. Upon advice of counsel, all persons who may have relevant knowledge pertaining to this matter include all parties and any person identified in any parties' answers to interrogatories and documents produced during the course of discovery, and any person identified in any deposition testimony, as well as all persons identified in any medical records, including plaintiffs' prior, concurrent and subsequent health care providers, and all persons identified as a result of continuing discovery.
12. None other than that which is contained within the chart.
13. Upon advice of counsel, NYU IVF Center records; records of Genesis Genetics, LLC; all records in connection with Chaya Grossbaum's pregnancy and delivery of the infant plaintiff, Rosie Grossbaum; other prior and subsequent treating records of both Chaya Grossbaum and Rosis Grossbaum; any documents identified by any party; and any documents to be identified as a result of continuing discovery.
14. Upon advice of counsel, information concerning proposed expert witnesses will be supplied in accordance with the applicable court rules.
15. Upon advice of counsel, information concerning proposed expert witnesses will be supplied in accordance with the applicable court rules.

CERTIFICATION

I hereby certify that the foregoing answers to interrogatories are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

I hereby certify that the copies of the reports annexed hereto provided by either treating physicians or proposed expert witnesses are exact copies of the entire report or reports provided by them.

Dated:

A handwritten signature in black ink, appearing to read "Mark R. Kohn", is written over a horizontal line.

INTERROGATORIES TO DEFENDANTS
GENESIS GENETICS AND MARK HUGHES

1. With respect to the persons hereinafter listed, set forth:

- (a) The date of employment by Genesis Genetics;
- (b) The date of termination at Genesis Genetics, if any;
- (c) Education, training and prior experience in genetic testing.

List of persons:

- (a) Shannon Wiltse;
- (b) Matt Studt;
- (c) Susan Brown.

2. Set forth the names of all medical institutions, clinics and genetic counseling services which have referred embryos to Genesis Genetics for PGD testing since the year 2000 to the present time.
3. Please attach a copy of the complete file maintained at Genesis Genetics for the Family Morganstern-Grossbaum.
4. Set forth whether there are any records maintained at Genesis Genetics concerning Family Morganstern-Grossbaum which were not contained within the chart provided in Defendant's answer to No. 3 above.
5. Set forth in detail the substance of all communications between persons connected to Genesis Genetics and persons connected with New York University Medical Center with regard to the Family Morganstern-Grossbaum, identifying the names of the communicants. Also, indicate the date and time of such communications and the method used.
6. Set forth and attach true copies of the billing records with respect to the PGD studies for the Family Morganstern-Grossbaum.

7. With respect to all lawsuits initiated against Genesis Genetics and/or Dr. Mark Hughes regarding PGD services, set forth the names of litigants, courts, docket numbers, and manner of disposition (settlement or judgment), date of conclusion of case, and name of attorneys for plaintiffs and defendants.
8. Set forth the names and addresses of all claimants, other than those persons mentioned in answer to No. 7 above, who made claims against Genesis Genetics and/or Dr. Mark Hughes that did not result in a lawsuit, and indicate whether any resulted in a settlement, the date of settlement, the amount of settlement, and the names of the attorneys representing the claimants.
9. Set forth the names and addresses of all expert witnesses who have provided opinions concerning PGD testing performed either for Genesis Genetics or Dr. Mark Hughes with respect to any lawsuits or claims made.
10. Attach a true copy of the current *curriculum vitae* of Dr. Mark Hughes indicating the following:
 - (a) Educational background;
 - (b) Places of employment;
 - (c) Medical institutions in which he had a relationship and the dates of commencement and ending of said relationship, if any;
 - (d) Places of licensure related to medicine;
 - (e) Action taken by any licensing or supervisory agency with respect to the suspension or supervision of medical practice of Dr. Mark Hughes;
 - (f) Whether Dr. Mark Hughes has been convicted of criminal behavior, and if so, set forth the court in which said conviction was recorded.
11. Set forth the names and addresses of all persons who have knowledge of facts relevant to this case who are otherwise not mentioned in the answers to the previous questions.

12. State: (a) the name and address of any person who has made a statement regarding this lawsuit; (b) whether the statement was oral or in writing; (c) the date the statement was made; (d) the name and address of the person to whom the statement was made; (e) the name and address of each person present when the statement was made; and (f) the name and address of each person who has knowledge of the statement.

Unless subject to a claim or privilege, which must be specified: (g) attach a copy of the statement, if it is in writing; (h) if the statement was oral, state whether a recording was made and, if so, set forth the nature of the recording and the name and address of the person who has custody of it; and (i) if the statement was oral and no recording was made, provide a detailed summary of its contents.

13. Identify all documents that may relate to this action, and attach copies of each such document.

14. State the names and addresses of any and all proposed expert witnesses. Set forth in detail the qualifications of each expert named and attach a copy of each expert's current resume. Also attach true copies of all written reports provided to you by any such proposed expert witnesses.

State the subject matter on which your experts are expected to testify.

State the substance of the facts and opinions to which your experts are expected to testify and provide a summary of the factual grounds for each opinion.

15. If you or your expert intends to rely on or use in any way at trial any treatise, book or journal article, identify the publication by title, author and edition and indicate the pertinent portions to be relied on or used at trial.

EXHIBIT 15



Professor Mark Hughes, MD, PhD
Director, Genesis Genetics Institute
Director, Applied Genomics Technology Center

Professor Mark Hughes graduated in Biology and Chemistry from **St. Johns University**, and then received a Masters in Biophysics at **Stanford University**, followed by a Ph.D. in Molecular Biochemistry at the **University of Arizona Medical Center**. He continued his training at the **Baylor College of Medicine** in Houston as a postdoctoral fellow with Bert O'Malley, where his pivotal work was published in *Science and Nature* and involved the cloning of the vitamin D and progesterone receptors and characterization of the first mutations found in human gene transcription factors. Following this training Hughes completed his M.D. at Baylor, followed by house staff training in Internal Medicine and clinical subspecialty training at **Duke University**. He then returned as junior faculty to Baylor's newly formed Genetics Institute led by Thomas Caskey. Among his accomplishments was the realization that single cells could be molecularly data mined for diagnostic advantage: This led to a multi-year collaboration with IVF clinicians and embryologists at the Hammersmith Hospital in London; the field of Preimplantation Genetic Diagnosis was born. *In 1993 Hughes' research was recognized by Science magazine as being one of the "ten most significant advances" in all of science that year; spanning all the physical, biological and mathematical sciences for that year.*

It was then that Professor Hughes was recruited to be one of the first 11 members of the **Human Genome Institute at NIH**. The Genome Project was getting underway and Hughes was recruited to lead the section on Translational Genomic Diagnostics. He also chaired Human Genetics at **Georgetown University**. Doctor Hughes then moved to Michigan to take a position as Professor and Director of Molecular Medicine and Genetics, Professor of OB-Gyn, and Professor of Pathology. He was named as the Director of the state of Michigan's 'Life Sciences Genomics Hub', focused on cutting-edge molecular medicine.

Hughes' work has centered on understanding gene expression in the early human embryo. His work on embryonic stem cells was acknowledged in 2001 when, along with Ian Wilmut (of Dolly the sheep fame) Hughes was awarded the "Pioneer in Stem Cell Biology" award. Professor Hughes, along with Professor Lord Robert Winston and Dr. Alan Handyside developed and performed the world's first cases of PGD. As we know, this field is now practiced world wide – today's speaker continues to push the frontiers of this technology and guide it in all its ethical ramifications, while he has expanded this work to systems-wide molecular understanding of early embryo development. His goal is to better understand, and hopefully prevent, many inherited birth defects of children. You may have seen him on the two hour BBC special, "Good Morning America", the "Today show", "CBS Evening News", and the subject of television newsmagazine segments for 60 Minutes and 20/20, and full hour programs on the Discovery Channel. His most recent medical advances have been in using Preimplantation Genetic Diagnosis to assist couples in avoiding serious diseases in their children and, at the same time, obtain a stem cell cure for a sick child already in the family. He performs this "miracle" every day now for hundreds of families. Four years ago, because of federal funding limitations on embryonic stem cell science, he moved the PGD aspects of his work into the Genesis Genetics Institute where the diagnostic aspects of PGD are provided to over 270 human reproductive centers in North and South America, Europe and now Asia.

Mark Hughes has an international reputation for his work on single-cell analysis and preimplantation genetic diagnosis. Through this work, Hughes diagnoses specific hereditary diseases in a single cell biopsied from an eight-cell embryo prior to implantation in the mother's uterus. This specialized procedure allows parents at high genetic risk to greatly reduce their odds of passing the genetic disease of concern on to their children.

Hughes graduated in Biology and Chemistry from St. Johns University, and then received a Masters in Biophysics at Stanford University, followed by a Ph.D. in Molecular Biochemistry at the University of Arizona Medical Center. He continued his training at Baylor College of Medicine where his pivotal work was published in *Science and Nature*. Professor Hughes completed his M.D. at Baylor, followed by house staff training in Internal Medicine and clinical subspecialty training at Duke University. He then returned as junior faculty to Baylor's newly formed Genetics Institute. Among his accomplishments was the realization that single cells could be molecularly data mined for diagnostic advantage. This led to a multi-year collaboration with IVF clinicians and embryologists at the Hammersmith Hospital in London; the field of Preimplantation Genetic Diagnosis (PGD) was born. *In 1993 Hughes' research was recognized by Science magazine as being one of the "ten most significant advances" in all of science that year; spanning all the physical, biological and mathematical sciences.*

It was then that Professor Hughes was recruited to be one of the first 11 members of the Human Genome Institute at NIH. The Genome Project was getting underway and Hughes was recruited to lead the section on Translational Genomic Diagnostics. He also chaired Human Genetics at Georgetown University. Doctor Hughes then moved to Michigan to take a position as Professor and Director of Molecular Medicine and Genetics, Professor of OB-Gyn, and Professor of Pathology.

In 2003, he moved the PGD aspects of his work into the Genesis Genetics Institute where the diagnostic aspects of PGD are provided to the most respected reproductive centers all around the world. Able to test for hundreds of genetic diseases, the Institute assists thousands of couples reach their dream of building a healthy family.

EXHIBIT 16

In The Matter Of:
Chaya Grossbaum and Menachem Grossbaum vs.
Genesis Genetics Institute, LLC, et al.

Samuel C. Pang, M.D.
November 23, 2010

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Videoconference Center
50 Franklin Street, Boston, MA 02110
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* * * *

16 "Deposition" is merely a three-syllable
17 word that means a question-and-answer session in
18 which you have been placed under oath here today,
19 and my questions and your answers are going to be
20 recorded by the lady who sits to my left and your
21 right. And if the matter goes to trial, what you
22 say here, to the extent that it may be inconsistent
23 with anything that you testify at trial, we can use
24 the deposition here today, that you give today.

Chaya Grossbaum and Menachem Grossbaum vs.
Genesis Genetics Institute, LLC, et al.

Samuel C. Pang, M.D.
November 23, 2010

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1 University Fertility Clinic?
2 A. I am familiar with the doctors who are
3 there.
4 Q. And can you tell me who you're familiar
5 with that are there.
6 A. Dr. Jamie Grifo and Dr. Fred Licciardi.
7 They are names that I know.
8 Q. And do you know them personally?
9 A. I do not have a personal relationship with
10 them.
11 Q. Have you met them individually?
12 A. I have met them to the extent that our
13 paths may have crossed at meetings.
14 Q. And did you know Dr. Hughes?
15 A. I do know Dr. Hughes.
16 Q. And can you tell me the circumstances under
17 which you know Dr. Hughes.
18 A. We work with Dr. Hughes for PGD.
19 MR. HAMAD: By "we," you mean the Center?
20 THE WITNESS: The Center.
21 MR. HAMAD: Sorry.
22 MR. STEIN: We're going to hopefully
23 establish a ground rule at the beginning of this
24 deposition that, as is frequently said, if you want

Page 10

1 to clarify anything that I fail to clarify, the
2 appropriate time, I believe, would be at the end of
3 the deposition. If you have an objection to my
4 question based on form, then please give that
5 objection by stating that, but more than that would
6 be considered a talking violation, okay?
7 MR. HAMAD: I apologize for the --
8 MR. STEIN: No apologies needed.
9 MR. HAMAD: -- offense.
10 MR. STEIN: We just want to be clear as to
11 the ground rules.
12 MR. HAMAD: Thank you.
13 BY MR. STEIN:
14 Q. And for how many years has the Reproductive
15 Science Center referred cases to Dr. Hughes for
16 laboratory studies?
17 A. I cannot give you an exact figure.
18 Q. Can you give me an approximation?
19 A. I can give you an approximation. It would
20 be in the range of six to eight years.
21 Q. And have you referred matters for
22 laboratory analysis to any other laboratory, other
23 than Genesis Genetics, for PGD purposes?
24 A. Yes.


Page 11

1 Q. And where is that?
2 A. Dr. Verlinsky's lab in Chicago and
3 Reprogenetics in New Jersey.
4 Q. Dr. Munne's lab?
5 A. Santiago Munne's lab.
6 Q. And can you tell me for how many years you
7 have been referring matters -- withdraw that
8 question. Do you still refer matters to Genesis
9 Genetics?
10 A. Yes.
11 Q. Can you tell me how frequently over the
12 last six to eight years you have been referring
13 matters for PGD to Genesis Genetics?
14 A. Again, I could not give you exact figures.
15 Are you asking on an annual basis or total --
16 Q. On an annual basis, your best estimate,
17 Doctor.
18 A. My best estimate on an annual basis would
19 be approximately 20 per year.
20 Q. And Dr. Verlinsky's lab in Chicago, for how
21 many years have you been referring matters there?
22 A. Again, I would have -- I could not give you
23 a specific figure, because I don't know the answer
24 to that, but I would estimate that it would be about

Page 12

1 the same time frame.
2 Q. And approximately how many patients do you
3 refer to the Chicago laboratory for PGD analysis on
4 an annual basis?
5 A. I could not give you a specific figure, but
6 I would have to estimate it is less than five per
7 year.
8 Q. Has it always been less than five per year,
9 or has that number changed over time?
10 A. I would say that it has always been less
11 than five per year.
12 Q. Can you tell me how you distinguish your
13 referrals as to whether they would go to Genesis
14 Genetics and Dr. Hughes or go to the Chicago lab of
15 Dr. Verlinsky.
16 A. It depends on different factors. There are
17 certain diseases where the lab in Chicago may have
18 an advantage for various reasons. There are also
19 situations where patients come to us having already
20 established a relationship with one or the other
21 lab, and we simply function as the IVF facility to
22 do the IVF process and the embryo biopsy process.
23 Q. What percentage of the cases that you get
24 involved with do patients already have an

EXHIBIT 17



Biological Discovery in Woods Hole

Founded in 1888 as the Marine Biological Laboratory

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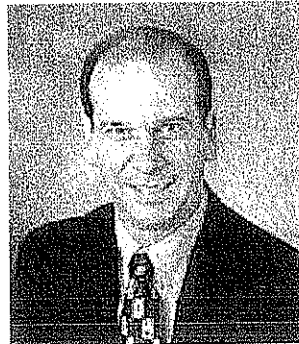
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Friday Evening Lecture Series



07/16/04

Preimplantation Genetic Diagnosis: The Technology, the Medicine and the Bioethics

Mark Hughes, *Genesis Genetics Institute*

Introduction by David Keefe, *Women & Infants Hospital, Rhode Island*

Lecture Abstract:

The completion of the Human Genome Project heralds a new era of Functional Genomics. Raw DNA information that comprises the blueprint of human life will be data-mined, taken apart, spliced together, and injected into cells, animals, and embryos in ways we can barely imagine. The promise is for new medicines, predictive diagnostic tests, and stem cell therapies. The potential for societal, legal, and ethical uses/abuses of this powerful information is especially strong in reproductive genetics involving human embryos and the developmentally totipotent cells derived from embryos. Most every American has a visceral and reflexive response regarding these promising yet troubling technologies. One such new technology is called "Preimplantation Genetic Diagnosis" (PGD) of the human embryo. PGD combines the technologies of in vitro fertilization (IVF), embryo culture and biopsy, and single-cell molecular genetics. It provides couples at high genetic risk the opportunity to begin their pregnancy on day-one, with the knowledge that their fetus will not have the inherited disorder that afflicts their family. No longer do they need to throw the genetic dice, take a chance, and consider amniocentesis. This talk will mesh the biomedical tools of IVF-PGD with the clinical genetic scenarios of desperate couples. The boundaries of testing for diseases versus traits will be explored with real-patient data.

Mark Hughes is a Professor and Director of Molecular Medicine and Genetics at Wayne State University and Director of the Genomics Center Hub for the State of Michigan's Life Sciences Corridor. Formerly at the Human Genome Institute at the National Institutes of Health, his work has centered on understanding gene expression in the early human embryo. He pioneered the field of PGD for couples at very high reproductive genetic risk and offers this technology in conjunction with IVF Centers in the U.S. and Canada. Last year he formed the Genesis Genetics Institute which performs human embryo testing for couples world-wide. Hughes earned dual bachelor of science degrees in Chemistry and Biology from St. Johns University in Minnesota, his Ph.D. in Biochemistry from the University of Arizona College of Medicine, and his M.D. from Baylor College of Medicine in Texas. He joined the faculty of Wayne State University in 1998. In 1993 Hughes' research was recognized by the prestigious *Science* magazine as being one of the "ten most significant advances" in all of science that year. Recently, a full one-hour *Discovery* television program was devoted to his research, and he has been featured on *Good Morning America*, the *Today Show*, *20/20* and this month was featured on *60 minutes II*.

David Keefe, M.D. will introduce Dr. Hughes. Dr. Keefe is the Director of the Division of Reproductive Medicine and Infertility and the Director of In Vitro Fertilization at Women and Infants Hospital in Providence, Rhode Island. He is also the Medical Director for the Division of Reproductive Medicine and Infertility at Tufts-New England Medical Center in Boston. Dr. Keefe's academic appointments include Research Affiliate in Obstetrics and Gynecology at Yale University School of Medicine, Associate Professor of Obstetrics and Gynecology at Brown University School of Medicine, Director of the MBL's Laboratory for Reproductive Medicine, and Adjunct Associate Professor of Obstetrics and Gynecology at Tufts Medical School. Dr. Keefe received his A.B. from Harvard College in 1976 and his M.D. from Georgetown University School of Medicine in 1980. He has served as the Director of the Society of Reproductive Endocrinologists and President of the Boston Fertility Society, which in 1997 gave him both its Prize Essay Award and its Original Research Prize. Dr. Keefe's other honors include the General Program Prize Paper of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology Prize Paper. Woodward/White, Inc.'s Best Doctors in America Award, the Science Coalition's Outstanding Research Breakthrough for 1998, and Brown Medical School's 2002-2003 Dean's Teaching Excellence Award. Dr. Keefe was named one of the 2000 Outstanding People of the 20th Century by the International Biographical Centre and he is listed in the 16th edition of *Who's Who in the World*.

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EXHIBIT 18

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
DOCKET NO. 07-cv-1359

CHAYA GROSSBAUM and MENACHEM
GROSSBAUM, her spouse,
individually, as guardians
ad litem of the infant, ROSIE
GROSSBAUM,

Plaintiffs,

v.

DEPOSITION OF:
DR. KANGPU XU

GENESIS GENETICS INSTITUTE,
LIC. of the State of Michigan;
MARK R. HUGHES, M.D., NEW YORK
UNIVERSITY SCHOOL OF MEDICINE
and NEW YORK UNIVERSITY
HOSPITALS CENTER, both
corporations in the State of
New York, ABC Corporation
1-10 and JOHN DOE 1-10,

Defendants.

TRANSCRIPT of testimony taken

Stenographically by and before PHILIP A. FISHMAN, a
Certified Shorthand Reporter and Notary Public of the
State of New Jersey, at the offices of LOWENSTEIN,
SANDLER, ESQs., 1251 Avenue of the Americas, New York,
New York on Thursday, May 17, 2010, commencing at three
o'clock in the afternoon.

PHILIP A. FISHMAN
COURT REPORTING AGENCY
89 Headquarters Plaza North
Morristown, New Jersey 07960
973-285-5331 - FAX 732-605-9391

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WITNESS DIRECT CROSS REDIRECT RECROSS

KANGPU XU

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BY Mr. Hamad 120

EXHIBITS

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APPEARANCES

NUSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON, ESQS.
20 Commerce Boulevard
Succasunna, New Jersey
BY: LEWIS STEIN, ESQ.
Appearing on behalf of the Plaintiff.

STEPHEN N. LEUCHTMAN, PC
1380 East Jefferson Avenue
Detroit, Michigan
Appearing on behalf of Genesis Genetics Institute
and Dr. Hughes

MARSHALL, DENNEHEY, WARNER, COLEMAN & GOGGIN, ESQS.
425 Eagle Rock Avenue
Roseland, New Jersey

BY: JAMELE A. HAMAD, ESQ.
Appearing on behalf of New York University School of
Medicine and New York University Hospitals Center.

KANGPU XU,

1300 York Avenue, New York, New York, having been duly
sworn according to law, testifies under oath as follows:

DIRECT-EXAMINATION BY MR. STEIN:

Q. Good morning, Dr. Xu.

A. Good morning.

Q. Am I pronouncing your name correctly?

A. Very accurately.

Q. We are here today to take your deposition, which
is merely a multi syllable word to describe a question
and answer session in which I am going to ask you some
questions and your answers and my questions are going to
be recorded by the gentleman who sits to my left and
your right, who is a Certified Shorthand Reporter.

At the end a booklet, a transcript of your
answers and my questions will be prepared for use in
this litigation.

To that end, I would like to give you a couple of
instructions.

A. Okay.

Q. One, it is not unlikely during this question and
answer session that I will ask you a question that makes
no sense to a specialist in genetics, since I am,
needless to say, not trained in that specialty, so if I

29

1 A. In my lab?
 2 Q. Yes.
 3 A. That will be true. That will be correct. Yes.
 Q. Okay. When is the first occasion that you used
 linkage analysis for a cystic fibrosis mutation?
 6 A. Mid 2000. Mid 2000, I would say.
 7 Q. When you say "mid 2000," what year are you
 8 referring to?
 9 A. I don't remember exactly what year unless I go
 10 back to look at our lab records.
 11 Q. Okay. Is it possible that you were doing linkage
 12 analysis in 2004?
 13 MR. LEUCHTMAN: Prior to 2004?
 14 Q. Yes.
 15 A. If retinoblastoma is one that we were looking,
 16 yes.
 17 Q. Okay. And is it possible that you were doing
 18 linkage analysis for cystic fibrosis in early 2004?
 19 MR. LEUCHTMAN: I object to the form of the
 20 question.
 21 It's speculation.
 22 A. I don't remember if we did.
 23 Q. Okay. Are you able to say definitely that you
 24 did not do linkage analysis for cystic fibrosis in the
 25 year 2003?

30

1 A. No, I can't say definite.
 2 Q. Do you routinely do linkage analysis for cystic
 3 fibrosis mutations currently in the year 2010?
 4 A. Yes.
 5 Q. And have you been doing it currently for several
 6 years now in cystic fibrosis?
 7 A. Several years, I would say, yes.
 8 Q. Okay. Have you ever been approached by other
 9 fertility centers to do PGD analysis for them?
 10 A. Yes.
 11 Q. And you have declined?
 12 A. Well, that's our center's policy. We decided not
 13 to take outside specimens.
 14 Q. Now, in connection with the operation of your
 15 clinic, do you yourself actually participant in the IVF
 16 process in either overseeing or participating in
 17 removing the eggs?
 18 MR. HAMAD: I object to the form.
 19 A. Yes, I do biopsy.
 20 Q. And after the biopsy is completed and the PGD
 21 study is done, do you counsel with the parents about the
 22 use of the embryos?
 23 A. No, I don't. I don't directly consult with the
 24 parents.
 25 Q. Do you meet with the parents at any time --

31

1 A. No.
 2 Q. -- during this process?
 3 A. No.
 4 Q. And who does that in your lab?
 5 A. Not the lab.
 6 Our center the physicians, the nurses and the
 7 genetic counselors and they usually have a geneticist at
 8 Cornell or outside.
 9 These are the people they will meet.
 10 Q. All right.
 11 Do you decide whether the PGD results are --
 12 create embryos and that are recommended to the family to
 13 be used?
 14 A. What --
 15 MR. HAMAD: Objection to form.
 16 You can answer.
 17 A. We produce the report and I sign the report and
 18 on the report we will recommend which one transfer or
 19 not transfer. Then the report goes to the embryology
 20 lab, and the embryology lab, physician, patient, those
 21 are the ones to decide which one to transfer.
 22 Q. Did you do follow-up to see the results of the
 23 IVF -- do you do follow-up to determine the results of
 24 IVF either with respect to the prenatal studies or the
 25 delivery of a live baby?

32

1 A. Our center work as a team. We have the nurses,
 2 we have genetic counselors and they do the follow-ups.
 3 Q. Thank you.
 4 And that's the policy of your center. Is that
 5 correct?
 6 A. That's the way we operate, yes.
 7 Q. And do you participate in establishing those
 8 policies and practices?
 9 A. Yes.
 10 Q. Okay. And why do you do follow-up for what
 11 purpose?
 12 A. Well, it's a quality assurance purposes. We try
 13 to improve constantly our services.
 14 That's the main purpose.
 15 Q. Now, are you familiar with the consent forms that
 16 the partners are required to sign when they undertake
 17 PGD testing?
 18 A. Yes.
 19 Q. And do those consent -- do you have any copies of
 20 those consent forms here?
 21 A. I don't have our center's consent, no.
 22 Q. Are you familiar with the consent form?
 23 A. Well, I don't remember all the details. Yes, I
 24 know what is the main part.
 25 Q. Okay. And is it a condition for you to provide

EXHIBIT 19

Strom

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1 IN THE UNITED STATES DISTRICT COURT

2 IN THE DISTRICT OF NEW JERSEY

3 -----x

4 CHAYA GROSSBAUM and MENCHEN

5 GROSSBAUM, Her Spouse, Individually

6 and as Guardian ad litem of the

7 infant, ROSIE GROSSBAUM,

8 Plaintiffs,

9 -against-

10 GENESIS GENETICS INSTITUTE, LLC, OF

11 THE STATE OF MICHIGAN, MARK R.

12 HUGHES, M.D., NEW YORK UNIVERSITY

13 SCHOOL OF MEDICINE and NEW YORK

14 UNIVERSITY HOSPITALS CENTER, both

15 corporations of the State of New York,

16 ABC CORPORATIONS, 1-10 and John Doe

17 DOE,

18 Defendants.

19 -----x

20 DEPOSITION OF CHARLES STROM

21 New York, New York

22 June 24, 2010

23 Reported by:

24 Judith A. Frost

25 Job No. NJ263710

Index No.

07-CV-359

Strom

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<p>1 2 3 4 5 June 24, 2010 6 9:13 a.m. 7 8 9 Continued videotape deposition of CHARLES 10 STROM, held at the offices of Lowenstein Sandler, 11 1251 Avenue of the Americas, New York, New York, 12 pursuant to Adjournment before Judith A. Frost, a 13 Shorthand Reporter and Notary Public of the State of 14 New York. 15 16 17 18 19 20 21 22 23 24 25</p>	<p>1 APPEARANCES: (Continued) 2 3 4 MARSHALL DENNEHEY WARNER COLEMAN & GOGGIN 5 Attorneys for Defendants New York University 6 School of Medicine and New York University 7 Hospitals Center 8 425 Eagle Rock Avenue, Suite 302 9 Roseland, New Jersey 07068 10 BY: JAY A. HAMAD, ESQ. 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>
Page 161	Page 163
<p>1 2 APPEARANCES: 3 4 NUSSBAUM STEIN GOLDSTEIN BRONSTEIN 5 & KRON, P.A. 6 Attorneys for Plaintiffs 7 20 Commerce Boulevard 8 Succasunna, New Jersey 07876 9 BY: LEWIS STEIN, ESQ. 10 LYNN HARRISON, PARALEGAL 11 12 13 TROWBRIDGE LAW FIRM 14 Attorneys for Defendants 15 Genesis Genetics Institute, LLC 16 and Mark Hughes, M.D. 17 1380 East Jefferson Avenue 18 Detroit, Michigan 48207 19 BY: STEPHEN LEUCHTMAN, ESQ. 20 21 22 23 24 25</p>	<p>1 CHARLES STROM, called as a 2 witness, having been duly sworn by a 3 Notary Public, was examined and testified 4 as follows: 5 EXAMINATION BY 6 MR. LEUCHTMAN: 7 THE VIDEOGRAPHER: The date is 8 June 24, 2010. The time on the monitor is 9 9:13 a.m. This is the beginning of tape 10 number one, volume two of the videotape 11 deposition of Dr. Charles Strom in the case 12 of Grossbaum, et al, vs Genesis Genetics, 13 LLC, et al. Index number 07-CV-359. This 14 case is filed in the United States District 15 Court for the District of New Jersey. We 16 are at the offices of Lowenstein Sandler 17 located at 1251 Avenue of the Americas, New 18 York, New York. 19 My name is Denrell Wright, and I 20 represent Veritext Video Production, and 21 counsel will please introduce themselves. 22 MR. STEIN: Steven Leuchtman, and I'm 23 sorry, usually I do plaintiff's work and I 24 typically introduce myself first. 25 I am Steven Leuchtman on behalf of</p>

Strom

<p style="text-align: right;">Page 180</p> <p>1 Mark Hughes' deposition, the second session, well, 2 you read them both? 3 A Right. 4 Q As we sit here today, are there any 5 areas of disagreement that you can recall subject to 6 Mr. Stein's objection as to the horrible unfairness 7 of the question, with the deposition of Dr. Hughes? 8 A There were several things of which I 9 disagree, but I don't remember in detail which ones. 10 Q What do you think even generally as we 11 sit here right now are the areas of disagreement 12 that you had with Dr. Hughes' opinions? 13 A The one I recall most was his 14 assertion that the use of linked markers for 15 protection of ADL was not well established at the 16 time. I take exception with that. 17 Q Do you know of your own knowledge 18 whether in and before 2004 that Dr. Dreesen's groups 19 were by biopsying two cells in order to establish 20 linked markers? 21 A I don't know for certain. 22 Q Again, realizing that you don't have 23 the deposition in front of you and it would be 24 burdensome and time consuming to have you reread it 25 at this juncture, is there anything else you can</p>	<p style="text-align: right;">Page 182</p> <p>1 A Yes, he didn't write his own report. 2 That has been established. 3 Q He signed off on? 4 A He didn't sign his own report. 5 Q I said signed off on. 6 A I said he didn't. I said somebody 7 else wrote it. 8 MR. HAMAD: Are you talking about the 9 expert report here or the report that was 10 sent that way? 11 THE WITNESS: The report that was sent 12 that way. He did sign the report, but he 13 didn't write his expert report. 14 Q So it would be speculation to say that 15 anything about the report that went to NYU affected 16 the result in this case, correct? 17 A Of course it affected the result. 18 Q How? 19 A Because that's what they use to 20 transfer embryos. The lab report. 21 Q The one page report? 22 MR. STEIN: Answer the question. You 23 nodded your head. 24 A Yes. 25 MR. HAMAD: Can we take a break?</p>
<p style="text-align: right;">Page 181</p> <p>1 think of specifically where you disagreed with Dr. 2 Hughes in his second deposition? 3 A There were definitely other things. I 4 did not believe his level of practice was 5 appropriate. But not outright disagreements. This 6 was a long time ago and I'm not sure. 7 Q Besides the issue of linked markers, 8 what issue do you take with the "level of practice" 9 demonstrated by Dr. Hughes in his second deposition? 10 A The lack of reconsenting the patient, 11 the lack of writing his own reports and the lack of 12 signing his own reports, the lack of writing his own 13 expert witness report. I felt those were all 14 inappropriate. 15 Q Did any of those affect the outcome 16 for the Grossbaums? 17 A Some of them may have. 18 Q I think you testified in your previous 19 deposition that you can't say that there is any 20 connection between the late consent? 21 A I said several things in that 22 sentence. 23 Q I'm trying to rule them out. 24 He wrote his report long after he had 25 any dealings with the Grossbaums, correct?</p>	<p style="text-align: right;">Page 183</p> <p>1 MR. STEIN: Let's go on. 2 MR. HAMAD: One minute break. 3 MR. STEIN: Why? 4 MR. HAMAD: I'm entitled to do that. 5 Steven, it's your deposition, would 6 you like a little break? 7 MR. LEUCHTMAN: I'll accommodate you, 8 Jay. 9 MR. STEIN: Are you requesting a 10 break? 11 MR. LEUCHTMAN: I'm not requesting a 12 break, no. I am consenting, if appropriate. 13 I'm going to defer to you. 14 MR. STEIN: I certainly object to this 15 type of intrusion on a deposition. The 16 witness is on the witness stand and giving 17 answers to questions and why are we taking a 18 break? 19 MR. HAMAD: Is there a time constraint 20 for the witness? 21 See you outside for a second? 22 MR. LEUCHTMAN: I do not want to get 23 myself in more trouble than Mr. Stein thinks 24 that I am in to begin with. 25 MR. HAMAD: There is nothing to get in</p>

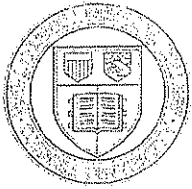
7 (Pages 180 - 183)

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EXHIBIT 20



Weill Cornell Medical College

NewYork-Presbyterian Hospital
Weill Cornell Medical Center

Kangpu Xu, Ph.D.
Director, Laboratory of Preimplantation Genetics
Associate Professor

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Fax: 212-746-8589
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The Center for Reproductive Medicine and Infertility
1300 York Avenue, P.O. Box 30
New York, NY 10065

February 26, 2010

Stephen N. Leuchtman, P.C.
1380 E. Jefferson Ave.
Detroit, MI 48207

RE: Grossbaum v. Genesis Genetics & Hughes

Dear Mr. Leuchtman,

Per your request, I have reviewed the following documents which you sent to me:

- 1) Medical Records of Genesis Genetics
- 2) Medical Records of IVF Center of New York University Medical Center
- 3) Reports from Dr. Garry R. Cutting and Dr. Charles M. Strom
- 4) Depositions of Mark R. Hughes, MD, PhD, Genesis Genetics; and Frederick Licciardi, MD, James Grifo, MD, PhD; Ms Alexis Adler, Kaycian Brown, R.N.; and Ms. Imelda Weill, New York University Medical Center
- 5) Depositions of Chaya Grossbaum (Volume 1 and 2) and Menachem M. Grossbaum.

As I understand, both Chaya Grossbaum and Menachem M. Grossbaum are carriers of a mutation for cystic fibrosis gene. They were referred to NYU IVF center and underwent IVF and biopsy at NYU and the specimens were sent and analyzed by Genesis Genetics. The child born from the procedure was found to be affected with cystic fibrosis.

As you probably know, I have been involved in PGD since 1992 when I was recruited as a faculty member at Cornell Medical College. I have published number of papers in PGD. For example, in 1993 we studied a new procedure, call Primer Extension Preamplification (PEP) for single human blastomeres. In particular we tested the most common CF mutation, delta F508, in the amplified products (Human Reproduction, 1993 vol.8, No.12, pp2206-2210). In 1999, we published the first successful PGD case for sickle cell anemia (JAMA). Again in 2004, first PGD for retinoblastoma was reported in American Journal of Ophthalmology. Furthermore, I am a certified laboratory directory by ABB (American Board of Bioanalysis) since 2002 and by New York State Department of Health as laboratory director since Oct. 5, 2004. My laboratory, Laboratory of Preimplantation Genetics, Center for Reproductive Medicine and Infertility, Weill Medical College of Cornell University, obtained permit for performing PGD for molecular testing since March 2006 and for



cytogenetics, since 2007. Beginning from 1995, as I was the head of the PGD program and later as the director of the laboratory at the Center for Reproductive Medicine and Infertility, Weill Cornell Medical College. We have completed over 1300 cases of PGD for variety of indications, including more than 70 cases for cystic fibrosis, covering more than a dozen of CF mutations.

Having known Dr. Mark Hughes as many years as I have been involved in PGD, he is, without any doubt, one of the most renowned pioneers in Preimplantation Genetic Diagnosis. He was the coauthor of the very first paper in the scientific literature described the success of PGD for cystic fibrosis (1992, New England Journal of Medicine). He was a member of President Bioethics Council that described the importance of PGD and recommended funding for PGD research in 1994. It is definitely not trivial that he was recognized and highly praised by the Jewish community, Bnei Olem, for his contribution to PGD (see Dr. Licciardi's deposition, page 25).

An open question and a central issue in PGD is that PGD has its limitations because it is a single cell based test. It has been recognized in the beginning of last decade in the PGD community that allele drop out (ADO), which occurs when low DNA copy numbers are used as the starting material for genetic testing, is a challenging issue. Numerous papers have been published in order to reduce or eliminate this inherent risk. Some proposed to biopsy two cells from one embryo, others tested different lysis strategies; still others were trying to use whole genome amplification to obtain more DNA for replicate testing. None of them appears to be fully effective. Current understanding is that ADO is a very complicated matter and there may be many contributing factors. ADO varies from cell type to cell type. ADO is usually low in the healthy cells, such as lymphocytes and fibroblast cells harvested at the growth phase. Likewise in blastomeres, ADO may also vary according the healthy status of the cells/embryos. It is not unreasonable that a healthy diploid blastomere (D3, 7-9 cell stages) provide lowest chance of ADO. Indeed, we have seen more aneuploidy/mosaicism in those slow developing or arrested embryos (4-5 cells on the morning of Day-3 post fertilization) in our FISH based aneuploidy tests.

Accumulated knowledge from the Human Genome Project facilitates the use of linkage markers which may reduce substantially the risk of ADO. Though it is highly desirable, markers are not always used even as of today for various reasons. Finding informative linkage markers is not trivial task or an overnight procedure. Building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, multiplex PCR was not the standard in 2004. During a period from 2001 to 2005, we successfully performed PGD for RB, an autosome dominant disorder with 50% risk without using markers. The reason was not that we were ignorant, but with the limitation that we had because we could not find markers that were informative for the couple. Three healthy singletons were born from 4 different IVF-PGD attempts. I believe tests conducted by Dr. Hughes were proper, appropriate and within the standard of practice existing at the time for this couple.

The tests performed on July 18-19, 2004 did statistically reduce the risk, from 25% to a much lower percentage. It was proper to recommend the transfer of embryo #7 and 8 based upon both reports issued by Dr. Hughes and Genesis Genetics on July 19, 2004. Results in both of Dr. Hughes' reports prepared on July 19, 2004 were within the accepted level of risk and the level of risk agreed to by the patients.

Another issue of embryological work using polar body biopsy is open for debate. Polar body biopsy or preconception genetic diagnosis was reported in 1990. However, the use of polar body biopsy has been limited in a few laboratories around the world. A few laboratories that performing polar body biopsy, such as those in Germany and Italy, not because of its superior strategy but because of their

country's law. As of today polar body biopsy for PGD is yet to be a mainstream approach (see a most recent debate article by Geradts et al. Human Reproduction, 2010, v25, pp575). It was not its technical difficult, but with its real benefits in routine PGD. If one looks ESHRE (European Society of Human Reproduction and Embryology) data collection from I to IX (the latest one), one could only find few cases PGD using polar bodies as testing materials. At CRMI, we performed PB biopsy in the late 90's for balanced translocation; the girl is now over 12 year old. Nevertheless, we have not, as most of the labs in the world, used PB biopsy as a routine procedure.

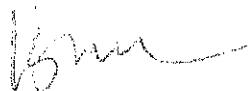
Because of the ever-present risk of ADO, and other risk factors inherent in PGD, CVS and amniocentesis are universally relied upon as a safety net in PGD. CVS has been shown to be very accurate. I know from my experience that Dr. Hughes and Genesis Genetics will not take on PGD of a couple if they will not agree in advance to CVS or amniocentesis; and this is appropriate and within accepted standards.

From the documents I reviewed I believe that the couple was well informed on many occasions that there were risks of misdiagnosis and they have signed at least two important PGD consents, one from NYU, and one from Hughes' team. Dr Hughes went all the details, as much as he could, with the couple. Specifically, and without going into every detail in the consent forms, the Grossbaums demonstrated an understanding that this is not a perfect technology, it is complicated, it is an experimental process, lowering the risk to zero is not realistic or possible, the technology can fail, and follow-up confirmation testing (in the form of CVS or amniocentesis) is necessary. The Grossbaums agreed to go forward in light of the risks and alternatives, and they agreed with both NYU and Genesis Genetics to undergo confirmation testing in the form of CVS or amniocentesis.

Because of so many variables involved in PGD, the cause(s) of PGD misdiagnosis is always difficult to pin down. Based on the literature most misdiagnosis is due to intercourse or unprotected sex. In a published data collection (ESHRE PGD consortium data collection VII: cycles from January to December 2004 with pregnancy follow-up to October 2005, Human Reproduction, 2008; Vol 23, No. 4, pp 741755), the best data collection and analysis in PGD community, the consortium stated on page 750 that "Eighteen misdiagnosis have been reported, 9 after PGD for PCR and 9 after PGD or PGS using FISH. In all cases of misdiagnosis, unprotected sex during the PGD cycle could be responsible as any embryos generated in vivo would not be tested." With this in mind, it is speculation to say that the bad result in this case was caused by the implantation of an affected embryo, as opposed to any of a number of other causes, including intercourse or unprotected sex by the Grossbaums.

In summary, I see a tragic case happened, not because of any negligence, but unfortunately because of the complexity and the limitations of the PGD technology and likely other confounding factors. Genesis Genetics did very professionally, and no deviations were seen from the standard of care.

Respectfully yours,



Kangpu Xu, Ph.D., HCLD.
Associate Professor
Director, Laboratory of Preimplantation Genetics
CRMI, Weill Cornell Medical College

EXHIBIT 21



March 2, 2010

Stephen N. Leuchtman, P.C.
1380 E. Jefferson Ave.
Detroit, MI 48207

RE: Grossbaum v. Genesis Genetics & Hughes

Dear Mr. Leuchtman,

As this case has progressed, I have been provided with and have read the following materials:

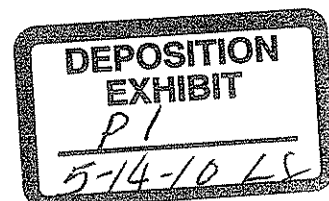
- 1) Medical Records of Genesis Genetics
- 2) Medical Records of IVF Center of New York University Medical Center
- 3) Reports from Dr. Garry R. Cutting and Dr. Charles M. Strom
- 4) Depositions of Mark R. Hughes, MD, PhD, Genesis Genetics; and Frederick Licciardi, MD, James Grifo, MD, PhD; Ms Alexis Adler, Kaycian Brown, R.N.; and Ms. Imelda Weill, New York University Medical Center
- 5) Depositions of Chaya Grossbaum (Volume 1 and 2) and Menachem M. Grossbaum.

Both Chaya Grossbaum and Menachem Grossbaum are carriers of a mutation for cystic fibrosis gene. They were referred to NYU IVF center and underwent IVF and biopsy at NYU and the specimens were sent and analyzed by Genesis Genetics. The child born from the procedure was found to be affected with cystic fibrosis.

I spoke with the Grossbaums on March 25, 2004 and explained to them in detail what was going to happen in the course of preimplantation genetic diagnosis (PGD). I explained that the technology involved is imperfect and pushes medical diagnostic technology to its absolute limit, its practical limit and its theoretical limit. I explained that PGD technology is in fact an experimental process, and that the technology can fail. I explained that the risk of natural pregnancy was that there was one chance in four that the baby would be afflicted with cystic fibrosis, whereas that risk could be significantly lowered by PGD, but not eliminated. Each test for the cystic fibrosis mutation(s) is custom-designed, so it is extremely difficult to predict the chances of success in any given implantation following PGD. I advised people in 2004 that the risk of having an affected child is three to five percent, and I am certain I imparted this to the Grossbaums.

Further, Genesis Genetics and I will not perform PGD for a couple who does not agree in advance to

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Detroit, MI 48213
313-579-9650 313-544-4006 fax
GenesisGenetics.org



March 3, 2010

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undergo chorionic villus sampling (CVS) or amniocentesis (amnio) early in the pregnancy. CVS is typically done at around ten weeks, and amnio is usually done at fifteen to sixteen weeks. I made the necessity of undergoing CVS or amnio known to the Grossbaums, and they agreed to this condition. At no time did they voice any objection or problem to me about CVS or amnio. Had they made any such objection, I would not have taken their case; and this fact was well known to NYU. I have had people over the years voice objections to amnio or CVS; and when this has happened, I have referred them to organizations who did not require conventional prenatal follow-up testing with amnio or CVS. It has always been an absolute, fully agreed upon, prior requirement of our program.

After the Grossbaums were informed about information including all of the above and more, they advised that they had no questions and were satisfied with what was going to be done. In May, 2004, I sent them a Preimplantation Genetic Diagnosis Patient Informed Consent, which the Grossbaums signed on June 4, 2004 and I countersigned on July 16, 2004. This Informed Consent included the following language, to which the Grossbaums agreed: "between ten and fifteen weeks of pregnancy you will undergo conventional prenatal genetic testing in the form of chorionic villus sampling (CVS) or amniocentesis. The sample will be used to confirm the predicted PGD test results." Based upon this written agreement following the oral agreement on March 25, 2004, I went ahead with PGD for this couple. My review of the NYU records and the depositions of the NYU people confirms that at no time did the Grossbaums ever voice any reservations to NYU about undergoing CVS or amnio.

As Dr. Kangpu Xu has pointed out in his report, an open question and a central issue in PGD is that PGD has its limitations because it is a single cell based test. It has been recognized since the beginning of last decade in the PGD community that allele drop out (ADO), which occurs when low DNA copy numbers are used as the starting material for genetic testing, is a challenging issue. Numerous papers have been published in order to reduce or eliminate this inherent risk. Some proposed to biopsy two cells from one embryo, others tested different lysis strategies, still others were trying to use whole genome amplification to obtain more DNA for replicate testing. Current understanding is that ADO is a very complicated matter and there may be many contributing factors. ADO varies from cell type to cell type. ADO is usually low in the healthy cells, such as lymphocytes and fibroblast cells harvested at the growth phase. Likewise in blastomeres, ADO may also vary according to the healthy status of the cells/embryos. It is not unreasonable that a healthy diploid blastomere (D3, 7-9 cell stages) provide lowest chance of ADO.

The use of linkage markers in 2004 for cystic fibrosis mutations was not standard of care in the field of PGD. Multiplex testing was done at the time in some laboratories for some diseases, but it was very new and experimental in early 2004, including when the Grossbaums underwent PGD and IVF. Even today for various reasons, these procedures are not in universal use. Finding informative linkage markers is not a trivial task or an overnight procedure. As Dr. Kangpu Xu has pointed out, building whole sets of linkage markers for each disorder/mutation is a continuing process. In 2004, not all the laboratories were using linkage markers and not for every single mutation; in other words, multiplex PCR was not the standard in 2004. I believe the tests conducted by my lab and myself were proper, appropriate and within the standard of practice existing at the time for this couple.

The tests performed on July 18-19, 2004 statistically reduced the risk, from 25% to much a much lower percentage. It was proper to recommend the transfer of embryo #7 and 8 based upon both

March 3, 2010

Page 3 of 3

reports issued by myself and Genesis Genetics. I prepared two reports on July 19. One was somewhat abbreviated; and the other went into greater detail. The results in both of my reports prepared on July 19, 2004 were within the accepted level of risk and the level of risk agreed to by the patients.

When I biopsy cells, I can comment to a degree on the likelihood that they will be affected or carriers of the disease we are looking for; but I cannot comment on the condition of the embryos on the day of implantation. Ultimately, the decision to go forward is that of the couple involved based on the best information their doctor and my lab and I can impart to them as of the day of implantation or transfer.

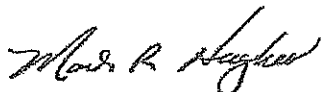
Dr. Kangpu Xu addresses polar body biopsy at great length in his expert report. I agree with his conclusions.

As alluded to above, because of the ever-present risk of ADO, and other risk factors inherent in PGD, CVS and amniocentesis are universally relied upon as a safety net in PGD. It was within the applicable standard of care for my lab and myself to insist upon agreement to CVS or amniocentesis as a condition to doing PGD. The Grossbaums agreed to go forward in light of the risks and alternatives, and they agreed with both NYU and Genesis Genetics to undergo confirmation testing in the form of CVS or amniocentesis.

As was pointed out by Dr. Kangpu Xu, because of so many variables involved in PGD, the causes of PGD misdiagnosis are always difficult to pin down. Based on the literature most misdiagnoses are due to intercourse or unprotected sex. In a published data collection (ESHRE PGD consortium data collection VII: cycles from January to December 2004 with pregnancy follow-up to October 2005, Human Reproduction, 2008; Vol 23, No. 4, pp 741755), the best data collection and analysis in PGD community, the consortium stated on page 750 that "Eighteen misdiagnosis have been reported, 9 after PGD for PCR and 9 after PGD or PGS using FISH. In all cases of misdiagnosis, unprotected sex during the PGD cycle could be responsible as any embryos generated in vivo would not be tested." With this in mind, it is speculation to say that the bad result in this case was caused by the implantation of an affected embryo, as opposed to any of a number of other causes, including intercourse or unprotected sex by the Grossbaums.

In summary, I believe that the unfortunate result in this case occurred, not because of any negligence, but unfortunately because of the complexity and the limitations of the PGD technology and likely other confounding factors. We acted professionally and at all times consistently with the standard of care as it existed at the time.

Very truly yours,



Mark R. Hughes

EXHIBIT 22

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
DOCKET NO. 07-CV-359

CHAYA GROSSBAUM and MENCHEN
GROSSBAUM, her spouse,
individually, as guardians ad
litem of the infant, ROSIE
GROSSBAUM, .

Plaintiffs,

DEPOSITION OF:

FREDERICK LICCIARDI

v.

GENESIS GENETICS INSTITUTE,
L.L.C., of the State of Michigan,
MARK R. HUGHES, M.D., NEW YORK
UNIVERSITY SCHOOL OF MEDICINE and
NEW YORK UNIVERSITY HOSPITALS
CENTER, both corporations in the
State of New York, ABC
CORPORATIONS 1-10 and JOHN DOE
1-10,

TRANSCRIPT of the stenographic notes of

the proceedings in the above-titled matter, as taken by

PHILIP A. FISHMAN, a Certified Shorthand Reporter and

Notary Public of the State of New Jersey, held at the

offices of Dr. Frederick Licciardi, 660 First Avenue,

New York, New York, on Wednesday, March 11, 2009,

commencing at 3:00 in the afternoon.

PHILIP A. FISHMAN
COURT REPORTING AGENCY
89 Headquarters Plaza North
14th Floor
Morristown, New Jersey 07960
(973)285-5331 - FAX (732)605-9391

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WITNESS DIRECT CROSS REDIRECT RECROSS

FREDERICK LICCIARDI

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by Mr. Eichhorn 77

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APPEARANCES:

NUSSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON, ESQS.
BY: LEWIS STEIN, ESQ.
Appearing on behalf of the Plaintiffs

STEPHEN N. LEUCHTMAN, P.C.
BY: STEPHEN N. LEUCHTMAN, ESQ.
Appearing on behalf of the Defendant Genesis Genetics
Institute, L.L.C., and Dr. Hughes

MARSHALL, DENNEHEY, WARNER, COLEMAN & GOGGIN, ESQS.
BY: R. SCOTT EICHHORN, ESQ.
Appearing on behalf of the Defendants New York
University School of Medicine and New York University
Hospitals Center

* * *

14:41:29 1 FREDERICK LICCIARDI, 660 First Avenue,
14:41:33 2 New York, New York, having been duly sworn according to
14:41:33 3 law, testifies under oath as follows:
14:41:34 4 DIRECT-EXAMINATION BY MR. STEIN:
14:41:34 5 Q. Dr. Licciardi, obviously, we are here to take
14:43:05 6 your deposition, which is just a multi-syllable word for
14:43:09 7 a question and answer session, in which my questions and
14:43:13 8 your answers are being transcribed by the gentleman who
14:43:15 9 sits to my left and your right, who is a Certified
14:43:19 10 Shorthand Reporter.
14:43:20 11 And if this case goes to trial, what you say here
14:43:24 12 may be used in court as evidence, so with those
14:43:30 13 instructions, let me tell you that you should treat this
14:43:33 14 question with the same seriousness as if you were giving
14:43:36 15 testimony in open court.
14:43:37 16 Do you understand that?
14:43:38 17 A. Yes.
14:43:39 18 Q. And, likewise, that's the reason you have been
14:43:43 19 placed under oath, and I am sure you understand the
14:43:46 20 meaning and significance of taking an oath before giving
14:43:49 21 testimony.
14:43:49 22 Is that correct?
14:43:50 23 A. Yes.
14:43:50 24 Q. Have you had the opportunity to give a deposition
14:43:56 25 in any other case before this?

15:24:44 1 A. I have met him.
 15:24:46 2 Q. Under what circumstances?
 15:24:48 3 A. There was a very large event held in his honor in
 15:25:00 4 Brooklyn about a year and a half ago and he was the
 15:25:05 5 honoree.
 15:25:09 6 Q. And what organization was giving him the honor?
 15:25:11 7 A. Bonei Olem.
 15:25:13 8 The spelling -- there is a plaque behind you that
 15:25:14 9 has the spelling.
 15:25:14 10 MR. EICHHORN: B-o-n-e-i, new word, O-l-e-m.
 15:25:20 11 Q. Can you tell me what type of organization Bonei
 15:25:23 12 Olem is?
 15:25:24 13 A. It's an orthodox Jewish religious organization
 15:25:29 14 that assists couples who need to become pregnant or they
 15:25:35 15 need genetic testing.
 15:25:42 16 Q. Okay. Have you yourself referred patients to Dr.
 15:25:50 17 Hughes or Genesis Genetics for PGD testing?
 15:26:00 18 A. I have.
 15:26:01 19 Q. On approximately how many occasions?
 15:26:03 20 A. A few.
 15:26:05 21 Q. Okay. Have you referred patients to any other
 15:26:11 22 genetic testing centers other than Dr. Hughes of Genesis
 15:26:15 23 Genetics for PGD testing?
 15:26:16 24 A. Yes.
 15:26:16 25 Q. And what centers?

15:26:20 1 A. Reprogenetics.
 15:26:21 2 Q. And that's located at Saint Barnabas?
 15:26:23 3 A. In New Jersey.
 15:26:24 4 Q. Livingston?
 15:26:26 5 A. Correct.
 15:26:27 6 Q. When was the last time you referred anyone to
 15:26:38 7 Genesis Genetics?
 15:26:39 8 A. I don't recall.
 15:26:42 9 Q. Have all of your patients, since 2005, been
 15:26:47 10 referred to the testing laboratory in Livingston
 15:26:54 11 Reprogenetics?
 15:26:55 12 MR. EICHHORN: Objection.
 15:26:56 13 You mean that he has referred?
 15:26:58 14 MR. STEIN: That he has referred, yes.
 15:27:00 15 A. I would have to check, because Reprogenetics
 15:27:05 16 doesn't test everything, and I may have referred a
 15:27:07 17 patient, but they may not have undergone the service.
 15:27:15 18 Q. And have the doctors here, in the Utility Clinic
 15:27:19 19 at NYU, ever had a meeting or discussion among the group
 15:27:25 20 of doctors concerning whether patients should be
 15:27:29 21 referred to Genesis Genetics for their PGD testing?
 15:27:39 22 A. I am not aware of that.
 15:27:39 23 Q. Have you ever made a determination not to send
 15:27:42 24 patients to Genesis Genetics at any time?
 15:27:48 25 A. No.

15:27:53 1 MR. EICHHORN: I am sorry, Lew, would you
 15:27:54 2 mind reaching into my jacket and getting that --
 15:27:57 3 that.
 15:27:58 4 (Whereupon, a discussion takes place off the
 15:30:14 5 record.)
 15:30:14 6 Q. Are you aware of any issues raised in the
 15:30:19 7 community of doctors which specialize in referring
 15:30:25 8 patients to PGD concerning problems with the studies
 15:30:28 9 done at Genesis Genetics?
 15:30:31 10 A. I am not.
 15:31:00 11 Q. Okay.
 15:31:47 12 (E-mail from Mark Hughes to Francis Hooper,
 15:31:53 13 dated March 25, 2004, is marked as Exhibit P-5
 15:32:03 14 identification.)
 15:32:46 15 Q. Doctor, I would like to show you both the e-mail
 15:32:49 16 marked P-4 for identification, which we previously
 15:32:52 17 discussed, and also P-5, which appears to be the record
 15:32:57 18 of another e-mail communication between Dr. Hughes and
 15:33:01 19 Francis Hooper.
 15:33:05 20 MR. EICHHORN: Can I just see P-5 for a
 15:33:07 21 second?
 15:33:08 22 Q. While counsel is looking at P-5, who is Francis
 15:33:12 23 Hooper?
 15:33:12 24 A. She is the assistant to Dr. Grifo.
 15:33:17 25 Q. Can you tell me how Dr. Grifo would be involved

15:33:20 1 with this patient?
 15:33:24 2 MR. EICHHORN: Well, are you asking him does
 15:33:25 3 he know how he was involved?
 15:33:27 4 MR. STEIN: The only thing I ever asked you,
 15:33:29 5 Doctor, is how you know.
 15:33:30 6 MR. EICHHORN: I don't think it was clear.
 15:33:32 7 MR. STEIN: Okay.
 15:33:32 8 MR. EICHHORN: Do you know how he was
 15:33:34 9 involved is the question.
 15:33:36 10 A. I will start by reading the memo.
 15:33:39 11 Q. Please.
 15:34:17 12 A. Okay. I am sorry. The question again.
 15:34:19 13 Q. How would Dr. Grifo be involved with this patient
 15:34:22 14 if she was your patient?
 15:34:24 15 A. Dr. Grifo is the director of PGD, so to speak,
 15:34:32 16 and his assistant handles the coordination -- some of
 15:34:36 17 the coordination of patients coming in for PGD, some of
 15:34:40 18 the logistics.
 15:34:41 19 Q. Okay. The job description or job title of being
 15:34:54 20 Director of PGD, does that indicate that Dr. Grifo has
 15:35:02 21 -- has more of the contact with the laboratories that do
 15:35:06 22 PGD analysis than you would have here?
 15:35:08 23 A. Yes.
 15:35:10 24 Q. Okay.
 15:35:35 25 A. I am sorry.

16:44:32 1 I hope it's the last time.
 16:44:35 2 It was about a minute and a half ago.
 16:44:37 3 MR. STEIN: We don't want you to know what
 16:44:40 4 we said.
 16:44:43 5 MR. LEUCHTMAN: All right.
 16:44:43 6 (Whereupon, a discussion takes place off the
 16:45:14 7 record.)
 16:45:14 8 Q. Now, Doctor, do you also see patients where one
 16:45:18 9 of the two parents has the cystic fibrosis gene?
 16:45:21 10 A. Yes.
 16:45:21 11 Q. About how many of those do you see a year?
 16:45:27 12 A. Five, estimate.
 16:45:29 13 Q. Do you normally send people, one of the parents
 16:45:32 14 who have tested for the presence of the cystic fibrosis
 16:45:37 15 gene, do you send them for PDG testing as well?
 16:45:40 16 A. No.
 16:45:41 17 Q. Because when you know that only one parent is a
 16:45:44 18 carrier, then the risk of having a cystic fibrosis baby
 16:45:50 19 is minimal. Is that right?
 16:45:51 20 A. Correct.
 16:45:53 21 Q. Are you aware at this institution of any
 16:45:58 22 situations in which people have been sent for PGD
 16:46:01 23 testing regarding the cystic fibrosis gene and they --
 16:46:05 24 and they had a cystic fibrosis baby, other than the
 16:46:09 25 Grossbaums?

16:46:10 1 A. I am not.
 16:46:12 2 Q. And that's over a period of how many years?
 16:46:19 3 A. Since we have started doing PGD. I don't know
 16:46:23 4 the exact date.
 16:46:23 5 Q. That would have been sometime in the early
 16:46:25 6 1900's?
 16:46:26 7 A. Yes.
 16:46:26 8 Q. Okay.
 16:46:36 9 Q. 1900's. I take it you have become aware --
 16:46:42 10 withdraw that question.
 16:46:43 11 I take it that you would become aware from your
 16:46:48 12 intradepartmental communications if any of the patients
 16:46:52 13 that were sent for PGD testing by your colleagues, as
 16:46:57 14 well as you, had the experience of having had parents
 16:47:05 15 who did have a cystic fibrosis baby?
 16:47:09 16 A. I may not have.
 16:47:10 17 Q. Can you tell me why you would not have?
 16:47:13 18 A. I don't know if I did or I didn't.
 16:47:16 19 Excuse me.
 16:47:17 20 I am not aware of any cases, but I can't attest
 16:47:23 21 to the fact that there were or there weren't.
 16:47:29 22 Q. Okay. Well, certainly, it's fair -- is it fair
 16:47:29 23 to infer that if there was a situation in which invitro
 16:47:36 24 fertilization was undertaken after PGD testing and the
 16:47:41 25 resultant baby suffered for the disease that the PGD

16:47:49 1 testing was done, that that would be a matter of serious
 16:47:52 2 concern to the department?
 16:47:58 3 A. Yes.
 16:47:59 4 Q. And so is it fair to say that would have
 16:48:02 5 generated then some intradepartmental discussion?
 16:48:10 6 A. Most likely.
 16:48:16 7 Q. When you found out that this baby had cystic
 16:48:19 8 fibrosis, did that generate some discussion in the
 16:48:22 9 department?
 16:48:22 10 A. Yes.
 16:48:24 11 Q. And did that discussion relate to the question of
 16:48:35 12 whether or not something was -- a mistake was made at
 16:48:35 13 Genesis Genetics?
 16:48:40 14 MR. LEUCHTMAN: I am going to object.
 16:48:41 15 I am not sure what the statute is in New
 16:48:43 16 Jersey, or if New Jersey law controls this case,
 16:48:49 17 but, generally speaking, morbidity and mortality
 16:48:53 18 conferences are exempt from discovery and
 16:48:56 19 certainly exempt from being testified to, so I
 16:48:59 20 maintain if there is no problem with this, a
 16:49:02 21 continuing objection to this line of questioning.
 16:49:05 22 MR. STEIN: Okay.
 16:49:08 23 Q. Can you answer the question?
 16:49:09 24 A. Repeat the question, please.
 16:49:11 25 (Whereupon, the court reporter reads as

16:49:29 1 requested.)
 16:49:29 2 MR. EICHHORN: Let me just -- if it's a
 16:49:32 3 quality assurance meeting, committee meeting,
 16:49:35 4 formal meeting of that type, I object also.
 16:49:38 5 If it's you and the other doctors talking, I
 16:49:43 6 don't have that objection.
 16:49:44 7 You can answer it subject to the objection
 16:49:47 8 that Mr. Leuchtman made and what I have said.
 16:49:50 9 A. There was an awareness of the child was born.
 16:49:53 10 However, that there was a -- there was not a discussion
 16:49:56 11 as to the circumstances of the cystic fibrosis child
 16:50:10 12 being born.
 16:50:11 13 Q. Okay. Now, do you have anything to do in your
 16:50:30 14 practice with obtaining a consent of the parents to PGD
 16:50:35 15 testing and invitro fertilization?
 16:50:38 16 A. For the invitro fertilization and PGD testing, we
 16:50:42 17 have a comprehensive initial consultation where I
 16:50:47 18 explain invitro fertilization, the risks, et cetera, et
 16:50:52 19 cetera.
 16:50:52 20 We have a team of people who orient the patients
 16:50:57 21 to invitro fertilization, PGD, and they are the ones who
 16:51:02 22 obtain the consent, the written consent.
 16:51:07 23 Q. And during the initial consultation, do you
 16:51:17 24 advise the parents that amniocentesis or CVA testing is
 16:51:24 25 mandatory as part of your program?

EXHIBIT 23

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
DOCKET NO. 07-CV-359

CHAYA GROSSBAUM and MENCHEM
GROSSBAUM, her spouse,
individually, as guardians ad
litem of the infant, ROSIE
GROSSBAUM,

Plaintiffs,) DEPOSITION OF:

v.)

JAMES GRIFO)

GENESIS GENETICS INSTITUTE,
L.L.C., of the State of Michigan,
MARK R. HUGHES, M.D., NEW YORK
UNIVERSITY SCHOOL OF MEDICINE and
NEW YORK UNIVERSITY HOSPITALS
CENTER, both corporations in the
State of New York, ABC
CORPORATIONS 1-10 and JOHN DOE
1-10,

TRANSCRIPT of the stenographic notes of
the proceedings in the above-titled matter, as taken by
PHILIP A. FISHMAN, a Certified Shorthand Reporter and
Notary Public of the State of New Jersey, held at the
offices of DR. JAMES GRIFO, 660 First Avenue, New York,
New York, on Wednesday, June 24, 2009, commencing at
4:00 in the afternoon.

PHILIP A. FISHMAN
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Appearing on behalf of the Plaintiffs

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BY: STEPHEN N. LEUCHTMAN, ESQ.
Appearing on behalf of the Defendant Genesis Genetics
Institute, L.L.C., and Dr. Hughes

MARSHALL, DENNEHEY, WARNER, COLEMAN & GOGGIN, ESQS.
BY: JAMELE A. HAMAD, ESQ.
Appearing on behalf of the Defendants New York
University School of Medicine and New York University
Hospitals Center

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WITNESS DIRECT CROSS REDIRECT RECROSS

JAMES GRIFO

by Mr. Stein 4

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EXHIBIT DESCRIPTION PAGE

JAMES GRIFO, 660 First Avenue, New York, New
York, having been duly sworn according to law, testifies
under oath as follows:

DIRECT-EXAMINATION BY MR. STEIN:

Q. All right.

Dr. Grifo, good afternoon.

As you know, my name is Lewis Stein.

I represent the plaintiffs, the Grossbaums, in
this lawsuit in which Genesis Genetics Institute and the
NYU Medical Center has been named as a defendant.

We are here today to take your deposition.

Have you ever had the pleasure of giving a
deposition before today?

A. Yes, sir.

Q. Could you just tell me generally what the
circumstances were in which -- in other words, what type
of case were you deposed in?

A. I don't recall the specifics. It was a medical
malpractice case.

Q. Did it involve the NYU School of Medicine program
for invitro fertilization and reproductive surgery and
fertility?

A. Yes, sir.

Q. About how long ago was that?

A. I don't recall. Several years. I don't recall.

1 Q. And can you tell me, generally, what the claim
2 was in that case?

3 A. The claim was a couple who delivered twins from
4 us. There was a discrepancy in the record regarding
5 identification of their frozen embryos. It was not an
6 embryo mix-up. They had healthy twins from us for that
7 cycle that were their twins. They insisted we mixed up
8 their frozen embryos, and sued us for that.

9 Q. And the claim was the healthy twins that they had
10 were not --

11 A. Were not their twins, but they were their twins.

12 Q. Were there any other occasions which you gave a
13 deposition relative to claims of medical negligence?

14 A. Maybe a long time ago one other. I can't even
15 recall what it was about. It was a case when I was a
16 resident.

17 Q. Okay. Back then it would not have been related
18 to, certainly, PGD testing?

19 A. No.

20 Q. Okay. Well, I am going to give you some
21 guidelines now with respect to the process, which I ask
22 you to follow and understand.

23 First, my questions and your answers are being
24 transcribed by the gentleman who sits to my left and
25 your right who is a Certified Shorthand Reporter, and in

1 the event that this case goes to trial, the transcript
2 may be used at that time, so even though we sit here in
3 a conference room at the Medical Center, you should
4 treat this question and answer session with the same
5 seriousness as if you were giving testimony in open
6 court.

7 Do you understand that?

8 A. Yes, sir.

9 Q. And that's the reason that you have been placed
10 under oath, and I take it that you understand the
11 obligations of the oath and the penalties with respect
12 to that process.

13 Is that correct?

14 A. Yes, sir.

15 Q. Further, that it is not unlikely that during the
16 course of this question and answer session, I ask you a
17 question that makes no medical sense, that likelihood is
18 heightened because it is not a general medical issue but
19 one relating to certain specific aspects of genetic
20 medicine, not being trained in medicine or in that area
21 of science, there is some concern that I will ask you a
question that makes no medical sense.

23 If that should happen, please indicate that to
24 me, and I would be happy to repeat the question,
25 withdraw it first, and give you an entirely new question

1 or I would change the question I ask you to try to make
2 it more meaningful.

3 Do you understand that?

4 A. Yes.

5 Q. If you do answer my question, both I and other
6 counsel do have a right to assume that you understand
7 the question.

8 Agreed?

9 A. Yes.

10 Q. A couple of more details.

11 There may come a time during this question and
12 answer session when the meaning of my question becomes
13 apparent to you before I finish speaking.

14 Please try to withhold your answer until I finish
15 speaking so that the reporter doesn't have to take both
16 of us speaking at once.

17 Also please answer all the questions verbally so
18 that the reporter doesn't have to try to interpret
19 either a gesture or less than a full verbal statement?

20 Understand?

21 A. Yes, sir.

22 Q. Okay. Doctor, are you currently the Director of
23 the Division of Reproductive and Endocrinology here at
24 NYU?

25 A. Yes, sir.

1 Q. And how long have you held that position?

2 A. Since August of 1995.

3 Q. Did you succeed anyone in that position when you
4 took over?

5 A. The previous division Director was Cecilly
6 Schmidt-Sorsi, S-c-h-m-i-d-t - S-o-r-s-i.

7 Q. Is she connected to the Medical Center?

8 A. Yes, sir.

9 Q. In what capacity?

10 A. Practicing physician.

11 Q. Okay. Can you tell me, when did NYU begin to
12 utilize PGD testing in its invitro fertilization
13 program?

14 A. Well, when we arrived in 1995, I brought that
15 technology with us. I was the first in the United
16 States to do that. I did it successfully at Cornell
17 University Medical Center in 1992. When I became the
18 division Director here, I brought the technology to NYU.

19 Q. The Cornell Medical Center, is that New York
20 Hospital?

21 A. New York Hospital.

22 Q. And now, in connection with doing PGD testing in
23 part of your program, have you had any experience, other
24 than with respect to the claims made by the Grossbaums
25 in this case, in which a baby was born from parents who

1 had genetic mutations that did have the condition or the
2 disease which the testing was designed or intended, at
3 least, to try to eliminate?

A. I am aware of one case.

Q. And what was the problem in connection with that
6 case?

MR. HAMAD: Objection to form.

You can answer.

A. The couple were carriers of familial
10 dysautonomia, and they had PGD, and the genetic test for
11 this couple would reduce their risk from a 25 percent
12 chance of having a baby down to the one or two percent
13 diagnostic accuracy that the scientific protocols allow
14 us.

These tests are not perfect, and, apparently,
16 there was the diagnostic occurrence that an embryo was
17 misdiagnosed and the baby was born with a disease.

Q. Prior to coming to NYU, while you were at
19 Cornell, did you have any experience in which the baby
20 had the disease, the condition for which PGD testing was
21 done and there was a failure of protection?

MR. HAMAD: Objection to form.

"Failure of protection," what does that
24 mean?

MR. STEIN: If the doctor doesn't know he

1 the baby was born with the disease?

A. I am not aware.

Q. Okay. When you answer that question, is there
4 any likelihood that you would be aware if that had
5 happened?

A. Not necessarily.

Q. Is there any program currently active which
8 collects data on what might be described as "failed PGD
9 testing" and the baby was born with the disease or
10 through amnio or CVS testing the baby was -- the fetus
11 was found to have the disease and it was aborted?

MR. HAMAD: Objection to form.

You can answer.

A. I don't know what you are asking.

Q. Well, is there any central location that collects
16 data with respect to the circumstances where there is a
17 PGD testing experience and the testing resulted in a
18 misdiagnosis for failure to identify the disease prior
19 to either the fetus being aborted or the baby being born
20 with the disease?

A. I am not aware of any agency that's designated as
22 such, but there are many publications in the medical
23 literature that have discussed the diagnostic
24 limitations of the technology where these kinds of
25 misdiagnosis have occurred, and it's kind of understood

10

1 can tell us.

That was the instruction at the beginning of
3 the questioning.

MR. HAMAD: Just so I can flush out my
5 objection here, again, with that in mind, please
6 try to use medical terms here in these questions,
7 obviously.

Doctor, if you understand what he is asking,
9 please try to answer it.

A. Well, I think I understand what he is asking.

At Cornell there was one patient who were
12 carriers of cystic fibrosis who terminated a pregnancy
13 that was thought to be genetically normal, but,
14 actually, thought to be carriers, but was affected, and
15 CVS testing was found to be affected and the pregnancy
16 was terminated.

That was about 1993 or four when the technology
18 was very young.

Q. Okay. Now, does Cornell at New York Hospital
20 still currently maintain a program of PGD testing in
21 connection with their invitro fertilization program, to
your knowledge?

A. Yes, sir.

Q. Are you aware of any situations at that hospital,
25 since you left, in which there was PGD testing and yet

12

1 among the field that this technology has a failure rate
2 associated with it in terms of the diagnostic accuracy
3 of the method. It's limited by the scientific basis for
4 testing single cell, and it's understood this is not 100
5 percent accurate, and that's why all the consents
6 reflect that and all patients are fully informed of that
7 possibility when they undergo this technology.

This technology offers them the option of
9 reducing their 25 percent inherent risk on natural
10 conception and reducing it to a much lower number, but
11 not to zero percent, and that's the unfortunate fact of
12 the science, and it also makes our job incredibly
13 difficult, because in our best attempts to help
14 patients, these kind of episodes that you see in this
15 case happened, and it's not a good situation for
16 anybody.

Q. Now, in connection with PGD testing, do you have
18 anything to do with selecting laboratories to whom the
19 embryos are sent for analysis?

A. That decision rests primarily with the physician
21 who is primarily taking care of the patient, because I
22 am so well recognized in the field, generally, the
23 majority of the PGD patients are seen by me, although my
24 colleagues in this institution are well versed in the
25 field and they are involved and there is lots of